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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,580	04/15/2004	Anja Kohlrausch	01-1491	8666

28501 7590 04/30/2008

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EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
04/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,580	KOHLRAUSCH, ANJA	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Amendment filed December 26, 2007 has been received and entered into present application.

Applicants' arguments, filed December 26, 2007, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Riedel et al. (US 2004/0259925 A1), already of record, for the reasons set forth at pages 2-3 of the previous office action, dated June 26, 2007, of which reasons are herein incorporated by reference.

In the previous office action, the rejection was incorrectly indicated as a 102 (a), and then relied on the filing date of art. The Riedel et al. patent application was filed on Jan 14, 2004. The office acknowledges that this is after the filing date of the provisional application (60/471,675) and the foreign priority document (German application No. 10319450.9). However, both the provisional and German patent applications are in German, with no English translation and with an English translation their contents cannot be verified and priority will not be given. Thus, the reference by Riedel et al. is proper prior art under USC 102 (e), at least until applicant has perfected priority to the provisional and/or German applications.

Applicant made no argument towards the teachings of Riedel et al. with regards to the instant invention, however for the sake of clarity it is noted that Riedel et al. teach crystalline telmisartan sodium salt (page 11, [0148]), in dosages of 20-200mg (page, 13, claim 15), and more preferably in dosages of 40mg and 80mg (example 4, page 11, [0140]-[0147]) as well as 10-50 mg of hydrochlorothiazide, and they teach dosages of 12.5 mg being most preferable (page 8, [0108]). They additionally teach the excipients claimed: Sorbital, mannitol, and magnesium stearate (page 7, [0083]), hydroxypropylcellulose and sodium starch glycolate (page 7, [0087]), as well as microcrystalline cellulose (page 7, [0088]). They also teach compressing the components into tablets (page 11, [0140]-[0147]) and thus claims 1-17 are anticipated by Riedel et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riedel et al. (US 2004/0259925 A1), already of record, for the reasons set forth at pages 2-3 of the previous office action, dated June 26, 2007, of which reasons are herein incorporated by reference.

In claims 18-19, applicant claims specific compositions, containing the active ingredients and specific excipients. Although Riedel et al. teaches the active ingredients and all the excipients claimed, they do not teach those specific combinations together explicitly. In example 4, tablet 3 (page 11, [0146]) they teach a composition of claim 18, containing telmisartan sodium salt, hydrochlorothiazide (the preferred diuretic), sorbitol, and magnesium stearate, which is compressed into tablets, however they do not explicitly state that the telmisartan sodium salt is the crystalline form. However, in the next example (tablet 5, page 11, [0148]) they teach the crystalline form, and thus it would have been obvious to one of ordinary skill in the art at the time of the invention that the crystalline form could be used in the composition of tablet 4.

In claim 19, applicant claims a composition comprising: cystalline telmisartan sodium salt, mannitol, magnesium stearate, and hydroxypropylcellulose, with hydrochlorothiazide, mannitol, microcrystalline cellulose, and sodium glycol starch. Riedel et al. teach the two active ingredients (telmisartan and hydrochlorothiazide), as well as all of the excipients as discussed above, however they do not teach that specific combination. The reference is not anticipatory insofar as one must "pick and choose" from different lists of excipients (page 7, [0084—[0091]). That being said, it would have been obvious in a self-evident manner to have selected mannitol from the diluents, magnesium stearate from the lubricants, microcrystalline cellulose and hydroxypropylcellulose from the binders, and sodium glycol starch form the disintegrants, Motivated by the unambiguous disclosure of each individually, and consistent with the basic principle of patent prosecution that a reference should be considered as expansively as is reasonable in determining the full scope of the contents within its four corners. Thus claim 19 is unpatentable over Riedel et al.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakatani et al. (US 2004/0110813 A1) in view of Donsbach et al. (US 2003/0130331 A1) in further view of Lacourciere et al. (Comparison of fixed-dose combination..) each already of record, for the reasons set forth at pages 3-6 of previous office action dated June 26, 2007, of which reasons are herein incorporated by reference.

As discussed in the previous office action (dated June 26, 2007), Nakatani et al. teaches a composition comprising 35-45 mg of telmisartan [0072], hydrochlorothiazide

[0078], and the excipients claimed. Specifically Nakatani et al. teaches sorbital [0023], magnesium stearate [0027], mannitol [0023], hydroxypropylcellulose [0025], microcrystalline cellulose [0025], and sodium glycol starch [0026]). Nakatani et al. fails to teach a specific dosage for hydrochlorothiazide, and they fail to teach the crystalline form of telmisartan.

As discussed in the previous office action dated June 26, 2007, Lacourciere et al. teach a composition for telmisartan and hydrochlorothiazide in which the dosage of telmisartan is 40 mg and the dosage of hydrochlorothiazide is 12.5mg. Since the two main components are the same as that taught in Nakatani et al., and the dosage for telmisartan is the same as that taught by Nakatani et al., it would have been obvious to one of ordinary skill in the art at the time of the invention that the dosage of 12.5 mg would be appropriate for use in the composition of Nakatani et al. Furthermore, Applicant's attention is drawn to MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages...Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Although the present claims are drawn to mg/day dosage amounts, such a motivation is nonetheless relevant.

Neither Nakatani et al. of Lacourciere et al. teach a crystalline form of the telmisartan sodium, however Donsbach et al. teaches a crystalline sodium salt of

telmisartan, as discussed in the previous office action dated June 26, 2007. Furthermore, Donsbach et al. teach the traditional spray drying process of making telmisartan results in limited solubility and is complex to prepare (page 1, [0006]-[0007], and they teach an easier means of preparing the composition by making a crystalline form telmisartan sodium (page 1, [0011]). They further teach that their crystalline form of telmisartan can be made into tablets (page 5, [0060]) and can be used with various excipients also taught by Nakatani et al. and the instant invention (page 5, [0061]). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention that it would be preferable to use the crystalline form of telmisartan sodium, for ease of preparation and better solubility, with the composition of Nakatani et al. and one of ordinary skill in the art would expect better results due to the increase solubility. Furthermore, all three references teach telmisartan for treatment of hypertension, and thus it would be obvious to combine the compositions as they are all directed towards a common goal. Applicant is reminded that "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Response to Arguments

Applicant has argued that none of the references cited teach the crystalline form of telmisartan sodium, however Donsbach et al. clearly teaches this crystalline form, and thus this argument is not found persuasive.

Applicant has also argued that there is no motivation for one of ordinary skill in the art to combine the references, which as discussed above is not true, due to the common ingredients in each composition, and the fact that all three compositions are directed towards treatment of hypertension, there is an obvious motivation to combine, as discussed above.

Applicant further argues that Donsbach et al. teaches away from the invention by teaching a spray drying method, however upon careful review of the reference, Donsbach et al. actually teaches that their crystalline method is better then the known method of spray drying, and thus teaches what the other references is lacking, and directly provides motivation to combine with the Nakatani et al. reference. This argument is not deemed persuasive, and the rejection of claims 1-13 under 35 U.S.C. 103 (a) over Nakatani et al. in view of Donsbach et al. in further view of Lacourciere et al. is **maintained.**

Conclusion

No claims are allowed.

Due to the change from U.S.C. 102 (a) to U.S.C. 102 (e) (claims 1-17) and U.S.C. 103(a) (claims 18-19) for the Riedel et al. rejection, this action is non-final, however the U.S.C. 103 (a) rejection over Nakatani et al. in view of Donsbach et al. is

maintained and the reasoning in the previous office action dated June 26, 2007 is still valid.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 7:30am-5pm Mon-Thu, 7:30am-4pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614